EU-AIMS Longitudinal European Autism Project (EU-AIMS LEAP): an exploratory study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Developmental disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON40536

Source
ToetsingOnline

Brief title
Leap

Condition

- Developmental disorders NEC

Synonym
Autism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Eli Lilly,Funded by Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115300;resources of which are

composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013),Hoffmann-La Roche,Janssen-Cilag

Intervention

Keyword: accelerated longitudinal study, autism spectrum disorder (ASD), biomarkers, MRI

Outcome measures

Primary outcome

Phenotyping of ASD will involve questionnaires and semi-structured interviews

probing the presence and severity of ASD. The MRI session includes structural

MRI, resting state, DTI and fMRI. Outside the scanner several computer based

tasks will be conducted to assess cognitive abilities. Eye-tracking and EEG

tasks will also be performed outside the scanner.

Secondary outcome

Not applicable

Study description

Background summary

Autism Spectrum Disorders (ASD) are a very heterogenous group of disorders characterized by qualitative impairments in social interactions and communication, and a range of repetitive and restricted behaviours and interests. Clinical diagnosis is still based solely on behavioural classification. No biomarkers have been established to aid in diagnosing or stratifying ASD.

Study objective

We aim to identify biomarkers (from neuroimaging, eye tracking, EEG, cognition, biochemistry, proteomics, genomics) for stratification of ASD. Biomarkers will be crucial to aid more accurate and earlier diagnosis of ASD. They are also needed for monitoring the effectiveness of new ASD treatments and for assessing the developmental trajectory of the disorder.

Study design

The study will be carried out at six study sites across Europe (Institute of Psychiatry, King*s College London (IoP / KCL), University of Cambridge (UCAM), University Medical Centre Utrecht (UMCU), Radboud University Medical Centre Nijmegen (RUNMC), Central Institute of Mental Health (CIMH, Germany), Karolinska Institute, Stockholm (KI), University Compus Bio-Medico (Italy)). Changes in ASD phenotype and biomarker profile will be assessed over time via an accelerated longitudinally design involving baseline assessment and follow-up at 12-24 months.

Study burden and risks

Children of 6-12 years will be included in this study, as we are investigating the development of autistic behaviour in childhood, as well as adolescence and adulthood. A study of young children through to adults is vital to understanding how the clinical and biomarker profile of ASD changes at different time points. Adolescent and adults with low IQ will be included as about 40% of all individuals with ASD have low IQ, and these are strongly underrepresented in all studies on ASD. By consequence, little is known about the cognitive, neural and biomarkers correlates of ASD in persons with low IQ. This work will lead to new biomarkers that will be essential for stratifying ASD, guide development of new drug treatments, and monitor course and clinical outcome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

ASD group:
(1) Males and females aged 6-30 years with an established diagnosis of Autism Spectrum Disorder according to DSM-IV; idiopathic and syndromic forms of ASD (e.g., Fragile X, Rett Syndrome) are allowed
(2) Males and females with IQ 50+
(3) All comorbidities (e.g., ADHD, anxiety) allowed except for psychosis and bipolar disorder
(4) Informed written consent;
(a) Where participants are their own legal guardian (i.e. aged 18 years and older without learning difficulties and demonstrated capacity to consent), written consent from the volunteer;
(b) Where participants are minors and/ or do not have capacity to consent, written informed consent from the parent or legal guardian; verbal assent from the volunteer prior to each assessment
(5) Availability of parent or caregiver who accompanies the volunteer to all institute visits and provides information about the volunteer*s behavior and symptoms. For adults with ASD who are their own legal guardian, availability of a parent who provides information about behavior/ symptoms during the institute visit, a separate home-visit or over the telephone.
(6) Participant on stable medication (min 8 weeks) at entrance point and over the course of study allowed
Typically Developing (TD) control group:
Males and females aged 6-30 years
Learning Difficulties (LD) control group:
Males and females aged 13-30 years
Syndromic forms of LD (Down*s Syndrome) and unspecified general learning disabilities allowed

Exclusion criteria

(1) Significant hearing or visual impairments not correctable by glasses or hearing aids
(2) Alcohol and / or substance abuse or dependence in the past year
(3) Any MRI counter-indications (e.g., metal implants, braces)
ASD and LD group: presence of psychosis or bipolar disorder
TD group: presence of any DSM-V axis I and II psychiatric disorders

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO Date:	15-11-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	17-02-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-06-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL45500.091.13